

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US00/21886

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) :A61K 31/13, 31/195

US CL :514/563, 641

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/563, 641

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- A	US 4,563,478 A (CURTI et al) 07 January 1986 (07.01.86), see the entire document, especially column 1, lines 15-48.	1-3, 5, 6, 9-13, 15-18 --- 4, 7, 8, 14, 19-26
X --- A	Database CA on STN, Chemical Abstracts Service (Columbus, Ohio, USA), No. 93:26054, KAPLAN et al. "New anticonvulsants: schiff bases of .gamma.-aminobutyric acid and .gamma.-aminobutyramide", abstract, J. Med. Chem., June 1980, 23(6), 702-4.	1-18 --- 19-26

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E* earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G* document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

19 OCTOBER 2000

Date of mailing of the international search report

20 NOV 2000

Noted by the ISA/US

Authorized officer

# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: ELLEN S. COGEN  
GIFFORD, KRASS, GROH, SPRINKLE, ANDERSON  
& CITKOWSKI, P.C.  
280 N. OLD WOODWARD AVE., SUITE 400  
BIRMINGHAM, MICHIGAN 48009

## PCT

### NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference UAB-15452/22	Date of Mailing (day/month/year) <b>20 NOV 2000</b>
International application No. PCT/US00/21886	International filing date (day/month/year) 10 AUGUST 2000
Applicant UAB RESEARCH FOUNDATION	

*Response out 12-20-00  
due 1-20-01*

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.  
 Filing of amendments and statement under Article 19:  
 The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):  

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO  
 34, chemin des Colombettes  
 1211 Geneva 20, Switzerland  
 Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.
2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
 

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.  
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.
4. Further action(s): The applicant is reminded of the following:  
 Shortly after 18 months from the priority date, the international application will be published by the International Bureau.  
 If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 bis 1 and 90 bis 3, respectively, before the completion of the technical preparations for international publication.  
 Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).  
 Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer <b>FREDERICK KRASS</b> Telephone No. (703) 308-1235
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## PATENT COOPERATION TREATY

RECEIVED  
MAY 16 2001  
GIFFORD, KRASS, GROH, SPRINKLE,  
ANDERSON & CITKOWSKI, P.C.  
PCTFrom the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: ELLEN S. COGEN  
GIFFORD, KRASS, GROH, SPRINKLE, ANDERSON  
& CITKOWSKI, P.C.  
280 N. OLD WOODWARD AVE., SUITE 400  
BIRMINGHAM, MICHIGAN 48009

NOTIFICATION OF TRANSMITTAL OF  
INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing  
(day/month/year)

11 MAY 2001

Applicant's or agent's file reference

UAB-15452/22

## IMPORTANT NOTIFICATION

International application No.

PCT/US00/21886

International filing date (day/month/year)

10 AUGUST 2000

Priority Date (day/month/year)

10 AUGUST 1999

Applicant

UAB RESEARCH FOUNDATION

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US

Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

FREDERICK KRASS

Telephone No. (703) 308-1235

# PATENT COOPERATION TREATY

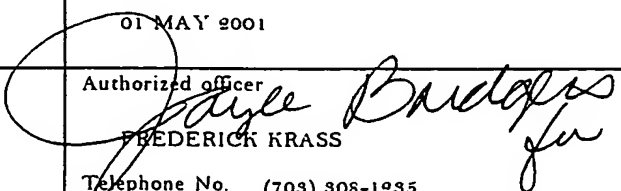
## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>UAB-15452/22</b>	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. <b>PCT/US00/21886</b>	International filing date (day/month/year) <b>10 AUGUST 2000</b>	Priority date (day/month/year) <b>10 AUGUST 1999</b>
International Patent Classification (IPC) or national classification and IPC <b>IPC(7): A61K 31/13, 31/195 and US Cl.: 514/563, 641</b>		
Applicant <b>UAB RESEARCH FOUNDATION</b>		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of <u>3</u> sheets.  <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  These annexes consist of a total of <u>0</u> sheets.
3.	This report contains indications relating to the following items: <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the report</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step or industrial applicability</li> <li>IV <input type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement</li> <li>VI <input type="checkbox"/> Certain documents cited</li> <li>VII <input type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul>

Date of submission of the demand  <b>02 MARCH 2001</b>	Date of completion of this report  <b>01 MAY 2001</b>
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  <b>FREDERICK KRASS</b>
Facsimile No. (703) 305-3230	Telephone No. (703) 306-1935

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/21886

**I. Basis of the report**1. With regard to the **elements** of the international application:\*☒ the international application as originally filed☒ the description:pages 1-20, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_☒ the claims:pages 21-25, as originally filedpages NONE, as amended (together with any statement) under Article 19pages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_☒ the drawings:pages 1, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_☒ the sequence listing part of the description:pages NONE, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. ☒ The amendments have resulted in the cancellation of:☒ the description, pages NONE☒ the claims, Nos. NONE☒ the drawings, sheets/fig NONE5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/21886

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. statement**

Novelty (N)

Claims	<u>1-26</u>	YES
Claims	<u>NONE</u>	NO

Inventive Step (IS)

Claims	<u>1-26</u>	YES
Claims	<u>NONE</u>	NO

Industrial Applicability (IA)

Claims	<u>1-26</u>	YES
Claims	<u>NONE</u>	NO

**2. citations and explanations (Rule 70.7)**

Claims 1-26 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest treating spastic disorders, convulsions, epilepsy, pain or dystonia using gamma-aminobutyramide or a compound which yields gamma-aminobutyramide following administration. (CURTI ET AL disclose compounds which yield GABA, not GABA amide, as an intermediate (column 1, lines 54-56). KAPLAN ET AL disclose Schiff bases of GABA amide, but it is not clear whether such compounds yield the amide upon administration, or some other intermediate).

Claims 1-26 meet the criteria set out in PCT Article 33(4); the applicability of the claimed methods to the pharmaceutical/medical industries is self-evident.

\_\_\_\_ NEW CITATIONS \_\_\_\_\_  
NONE